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	ANSMITTAL LETTER	P/2432-38					
	DESIGNATED/ELECT	U.S. APPLICATION NO. (If known, sec 37 CFR 1.5)					
	CONCERNING A FILI	077703312					
1	TIONAL APPLICATION NO. SE99/01354	INTERNATIONAL F 9 August		PRIORITY DATE CLAIMED 19 August 1998			
TITLE OF INVENTION TRANSPORTABLE APPARATUS FOR TREATING MENIERE'S DISEASE							
APPLICANT(S) FOR DO/EO/US Daniel ENGVALL and Anders NILSSON							
Applicant	herewith submits to the United State	es Designated/Elected C	Office (DO/EO/US) the follo	owing items and other information:			
i. 🔀	This is a FIRST submission of item	is concerning a filing ui	nger 35 U.S.C. 371.				
2.	This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.						
3. X	This is an express request to promp	tly begin national exam	unation procedures (35 U.S	.C. 371(f)).			
4.	The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).						
5. X	A copy of the International App	lication as filed (35 U	J.S.C. 371(c)(2))				
	a. is attached hereto (requ	ired only if not comr	nunicated by the Interna	tional Bureau).			
	b. X has been communicate	d by the International	l Bureau.				
	•		n the United States Rece	_ ` ` '			
6.	An English language translation						
7	Amendments to the claims of the						
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	b. have been communicated by the property and the beauty and the property and the beauty and the	•		menta has NOT avaired			
	c. L have not been made; however, the time limit for making such amendments has NOT expired.						
۰П	d. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3))						
	An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).						
<i>7.</i> 🗀	An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).						
10. 本区	An English language translation PCT Article 36 (35 U.S.C. 371)		e International Preliminar	ry Examination Report under			
Items 1	1 to 16 below concern documen	t(s) or information i	ncluded:				
11.	An Information Disclosure State	ement under 37 CFR	1.97 and 1.98.				
12.	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.						
13. KX	A FIRST preliminary amendment	nt.					
	A SECOND or SUBSEQUENT	preliminary amendm	ent. EXPRESS N	MAIL CERTIFICATE			
14.	A substitute specification.		I hereby cert	tify that this correspondence is being			
15.	A change of power of attorney and/or address letter. deposited with the United States Postal Service as Expression Mail Post Office to Addresses (mail label)						
16. KX	Other items or information:	,	EL613112996US	in an envelope addressed to: for Patents, Washington. D.C. 20231,			
	3 sheets of draw	ings.		y 20, 2001			
			Dorothv	Jenkins			
				rson Mailing Correspondence			
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			February				
			Date of Sign	tature			

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17. X The followin	a fees are submitter		CA	LCULATIONS		
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CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE			
Total claims	8 - 20 =	0	X \$18.00	S		
Independent claims	1 -3 =		X \$80.00	S		
MULTIPLE DEPENDE			+ \$270.00	S		
	TOTAL	OF ABOVE CALCULA	TIONS =	\$	1000.00	<u> </u>
Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.					500.00	
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P/2432-38

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

New York, New York

Daniel ENGVALL et al

Date: February 20, 2001

Serial No.:

Group Art Unit:

Filed:

Examiner:

For: TRANSPORTABLE APPARATUS FOR TREATING MÉNIÈRE'S DISEASE

Asst. Commissioner for Patents

Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination, please amend the application as follows:

IN THE CLAIMS:

Please amend claims 4-8 as follows.

Claim 4, line 1, change "any of claims 1-3" to --claim 1--.

Claim 5, line 1, change "any of claims 1-3" to --claim 1--.

Claim 6, line 1, change "any of claims 1-5" to --claim 1--.

Claim 7, line 1, change "any of claims 1-6" to --claim 1--.

Claim 8, line 1, change "any of claims 1-7" to --claim 1--.

REMARKS

This Preliminary Amendment is submitted to change the multiple dependent claims to single dependent claims in order to eliminate the improper multiple dependent claims and to reduce the government filing fee.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Post Office to Addressee (mail label #EL613112996US) in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231, on February 20, 2001:

Dorothy Jenkins

Name of Person Mailing Correspondence

Signature February 20, 2001 Date of Signature

Respectfully submitted,

Registration No.: 24,322

OSTROLENK, FABER, GERB & SOFFEN

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Telephone: (212) 382-0700

WO 00/10484

TRANSPORTABLE APPARATUS FOR TREATING MÉNIÈRE'S DISEASE

FIELD OF THE INVENTION

5

The present invention relates to a transportable apparatus for treating Ménière's disease and similar conditions which affect the pressure balance between the various compartments of the internal ear.

10

BACKGROUND OF THE INVENTION

Ménière's disease can be treated by affecting the pressure in the internal ear, in particular the endolymphatic system.

15 A number of apparatus for carrying out this treatment are known in the art. The comprise a pressure generating/control unit to which a flexible tube provided with an ear plug is coupled for conducting pressure pulses to a patient's external ear.

20

WO 83/02556 discloses an apparatus for influencing the hydrodynamic system of the inner of an ear comprising a displaceable diaphragm forming the wall of an air pressure generating chamber, the diaphragm being reciprocally

25 displaceable by means of a crank coupling in a direction away from the chamber against the force of a spring coil.

WO 93/08775 discloses an air pressure generator for the treatment of Ménière's disease by pressure pulses generated

- 30 by a flexible membrane forming a wall in a pressure generating chamber, the membrane being displaced by actuation means rigidly coupled to the shaft of an electrical motor.
- 35 WO 97/23178 discloses a device for affecting the hydrodynamic system of the inner ear comprising first means

for generating a static pressure level and second means for causing a variation of that level in accordance with a predetermined program controlled by a control unit. Each of the first and second means comprise a flexible membrane.

- 5 Also in this known apparatus one half of the reciprocating movement of the diaphragm, the one in which the diaphragm moves towards the pressure generating chamber, is caused by spring means.
- 10 The design of these apparatus is silent about the patient's need for ambulant treatment. To allow the patient to live a life as normal as possible and, in particular, to travel, it should be possible to administer the treatment wherever the patient happens to be. Since such administration implies
- that that it would have to be carried out in the absence of competent health care personnel self-administration should be possible. A transportable apparatus for personal use should also be of a design protecting its delicate parts and the flexible tube/earplug from damage and dirt, and its
- 20 maneuver organs from inadvertent manipulation.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an

25 apparatus for treatment of Ménière's disease and similar

conditions by affecting the pressure in the internal ear

which is easy to transport by the patient to be used

whenever there is a need for treatment, and which takes into
account and solves the aforementioned design problems.

30

It is another object of the invention to provide such an apparatus which, in addition, can be operated by the patient without assistance by others.

her.

WO 00/10484 PCT/SE99/01354

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SUMMARY OF THE INVENTION

According to the present invention is provided an apparatus of the aforementioned kind, comprising electronically 5 controlled pressure variation means housed in an inner casing, the inner casing being partially enclosed by an outer casing provided with an opening covered by a removable cover, a storage compartment disposed between the casings, a flexible tube connected to said pressure variation means at 10 its one end and being provided with an ear plug at its other end, the flexible tube being disposable in the storage compartment and removable therefrom with its free end carrying the ear plug for administration of pressure pulses to the external ear of a patient. This solves an important 15 problem since the flexible tube has to be about half a meter long at minimum to allow its ear plug to be fixed to the patient's external ear. If not stored and protected properly it would have a tendency to intertwine and fasten with the ear plug in other gear. This tube length is required for 20 convenient self treatment during which the patient sits at a table while the apparatus rests on the table before him or

According to a preferred aspect of the invention the storage 25 compartment surrounds a first portion of the inner casing; preferably the flexible tube is disposed in a coiled manner around that portion. This design provides additional shielding for the most sensitive elements of the apparatus while providing for easy deposition of the tube after a 30 treatment session.

According to a second preferred aspect of the invention the first portion of the inner casing is removable from a second portion of the inner casing. Preferably the second portion

4

of the inner casing and the outer casing are made from one piece of material. By removing the first portion of the inner casing the electronics and the mechanical parts of the apparatus become accessible for adjustment or repair by a technician without having to disassemble the apparatus. Electronic and mechanical elements of a delicate nature can be disposed in a way that makes them face the first portion. Thereby they are optimally protected by being mounted in the innermost part of the apparatus while remaining easily accessible from outside for repair and testing.

Also preferred is to make the flexible tube pass through an opening in the first portion of the inner casing.

15 According to a third preferred aspect of the invention the first portion of the inner casing is provided with a panel for control of the apparatus by the patient. Thereby an inadvertent start or other manipulation of the apparatus' maneuver organs is prevented.

20

To protect the patient from damage the apparatus of the invention is confined to working pressures not exceeding 30 cm of water column. This is achieved by providing the apparatus with a pressure sensor and to program the 25 microprocessor to open a safety valve once the maximum

Advantageously the apparatus of the invention comprises a rechargeable battery in a battery compartment and an electrical connector for connection to a battery eliminator.

tolerable pressure is reached.

The battery compartment is advantageously disposed in a way to make it accessible from the rear (bottom) side of the apparatus, that is, the side on which the apparatus stands when in use.

Further preferred features of the present invention are disclosed in the appended claims and a preferred embodiment illustrated in a rough drawing, in which is shown in

- 5 Fig. 1 the apparatus of the invention, in a side view from above, with the casing cover in an open position, and with the flexible tube in a stored (coiled) condition;
- 10 Fig. 2 the apparatus of Fig. 1 and in the same view, with the flexible tube provided with an earplug in an uncoiled position ready for connection to the external ear of a patient;
- 15 Fig. 3 the apparatus of Fig. 1, in a vertical section along its largest diameter, without the flexible tube and with the cover in a closed position.
- The apparatus of the invention shown in Figs. 1-3 comprises
 20 an inner casing 1 of having about the form of an ellipsoid
 delimited by two bases perpendicular to its the axis of
 symmetry and thus parallel to each other. One end portion of
 the inner casing 1 is surrounded by the wall of an outer
 casing 2 which is also ellipsoid in form and shares the axis
- 25 of symmetry casing 1. The ellipsoid wall of the outer casing 2 is spaced apart from the inner casing 1 to which it is joined by a bottom flange 3 forming the peripheral part of what would be its one basis. Thereby an annular space or groove 6 of elliptic form is formed. Any other suitable
- 30 form of the apparatus, such as a circular form, would be equally possible.

The other (topside) basis of outer casing 2 is lacking.

Instead the outer casing 2 is provided with an elliptical

flat cover 4 fastened by a hinge 14 to let it be opened and closed. For most of its circumference, except for a portion in the proximity of the hinge 14, the cover 4 is provided with a rim 15 which overlaps a the outer casing 2 wall when 5 the cover 4 is in a closed position in which it can be releaseably secured to the outer casing 2 (not shown). A simple snap lock (not shown) holds the cover 4 in the closed position; it is moulded into appropriate superimposed (when closed) portions of the inside of rim 15 and the outside of the cuter casing 2 wall.

The inner casing 1 contains a pressure generating unit 7 for generating the variations in air pressure to be adduced to the external ear of a patient and, from there, to the

- 15 patient's internal ear through a tiny tube implanted in the tympanic membrane. The pressure generating unit 7 may comprise a diaphragm pump operated by electrically driven actuating means, such as the assembly disclosed in WO 97/23178. It is only indicated in a general way in Fig. 3.
- The pressurized air outlet of the pressure generating unit 7 has the form of a nipple 10 suitable for attaching one end of a flexible plastic tube 11 the other end of which caries an earplug 13 to be inserted into one of the the patient's external ears.

25

The flexible tube 11 extends through a circular opening 8 into the elliptical circumferential groove 6 in which it can be wound up when the apparatus of the invention is not being used. This condition is shown in Fig. 1. The free end 12 of the flexible tube 11 normally carries an earplug 13 which has been omitted in Fig. 1 for reasons of clarity. Though being substantially thicker than the flexible tube 11 the earplug 13 can also be stored in the elliptical groove 6 by

a design making the groove to widen at a portion 9 of the inner casing 1 wall deviating in the direction of the axis of symmetry of the ellipsoid; the opening 8 is arranged in this wall portion 9.

5

- Fig. 2 shows the apparatus of the invention ready for use. The flexible tube 11 is unwound and disposed for most of its length outside of the apparatus of the invention.
- 10 The apparatus in Figs. 1-3 is intended to be put on a horizontal support with its flat underside, the basis pertaining to the portion of the inner casing 1 extending exteriorly of the outer casing 2.
- 15 In addition the inner casing 1 houses an only schematically illustrated electronic control unit 17 including a microprocessor for controlling the generation of the pressure pulses in the pressure generating unit 7. Energy for several treatments can be stored in rechargeable
- 20 batteries 23 disposed in a separate battery compartment 24 accessible from the underside of the apparatus by removing the compartment lock 25. Miniature contacts accessible from outside for recharging the batteries 23 through a battery eliminator are not shown in the Figures; the same is true
- 25 for other electrically operated equipment known in the art, such as a valve for equalizing air pressure in the pressure generating unit 7 and a safety valve.
- The top wall 5 of the inner casing 1 is provided with a panel 18 for operation of the apparatus by the patient. The panel 18 comprises an on/off touch switch 19 and four diode lights 20 indicating, to the patient: whether the apparatus is pumping or not; the completion of a treatment session;

 that the manual should be consulted; that there is a leakage.

The portion of the inner casing 1 enclosed by the outer

5 casing 2 is mounted by screws 22 to the combination of the
not-enclosed portion of 2 and the outer casing 1 which is
made in a single piece of a hard polymer material; the same
material is used for said mounted portion of the inner
casing 2 and the outer casing cover 4. This design provides
10 convenient access to the various parts housed in the inner
casing 1.

The apparatus of the invention can be made to a size and a weight which make it convenient to carry. The casings can be 15 manufactured by injection moulding from a variety of polymer materials. A prototype of weighing about 550 g has been tested in patients with good results.

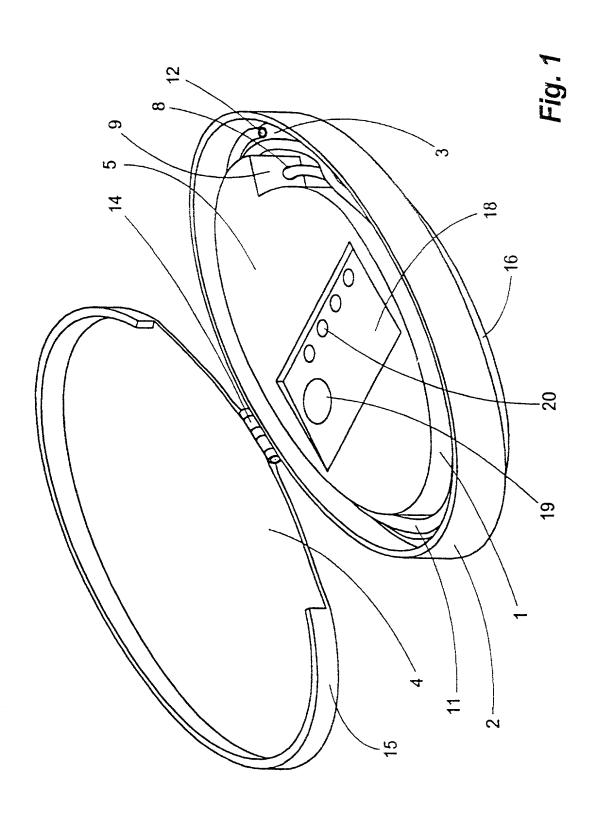
Claims

- 1. A transportable apparatus for treating Ménière's disease and similar conditions affecting the pressure
- balance between the various compartments of the internal ear, comprising electronically controlled pressure variation means housed in an inner casing, the inner casing being partially enclosed by an outer casing provided with an opening covered by a removable cover, a storage compartment
- 10 disposed between the casings, a flexible tube connected to said pressure variation means at its one end and being provided with an ear plug at its other end, the flexible tube being disposable in the storage compartment and removable therefrom with its free end carrying the ear plug
- 15 for administration of pressure pulses to the external ear of a patient, said storage compartment surrounding a first portion of the inner casing around which the flexible tube is disposable in a coiled manner.
- 20 2. The apparatus of claim 1, wherein said first portion is removable from a second portion of the inner casing.
- 3. The apparatus of claim 2, wherein said second
 25 portion of the inner casing and the outer casing are made from one piece of material.
- 4. The apparatus of any of claims 1-3, wherein said first portion of the inner casing is provided with a panel 30 for control of the apparatus by the patient.
 - 5. The apparatus of any of claims 1-3, wherein the flexible tube passes through an opening in said first portion of the inner casing.

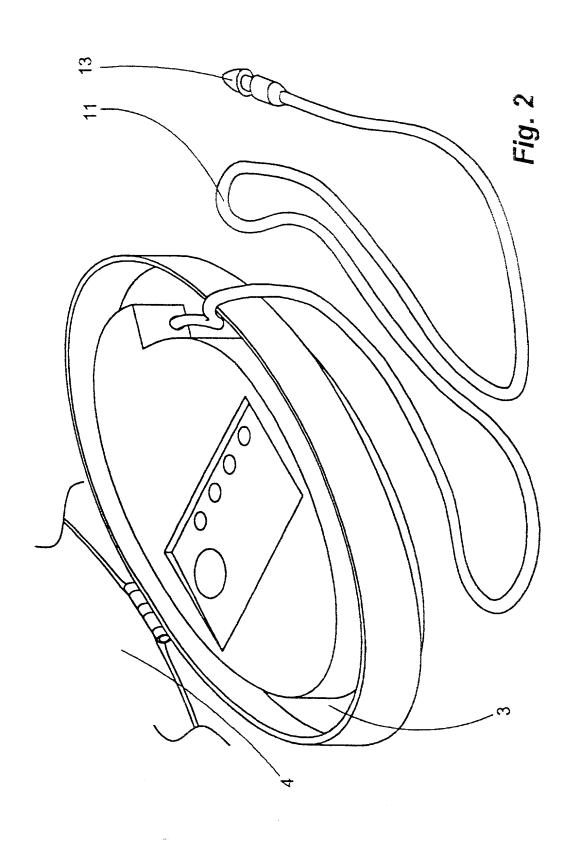
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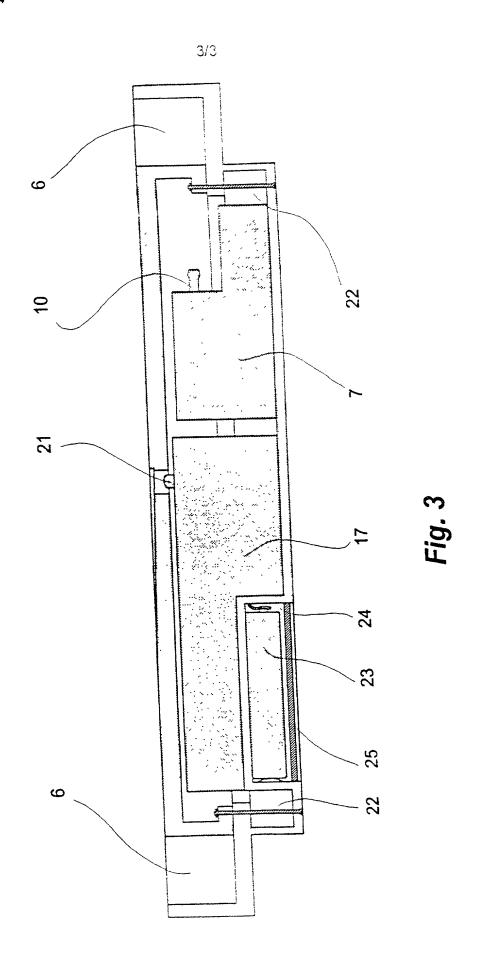
- 6. The apparatus of any of claims 1-5, wherein the pressure pulses do not exceed 30 cm of water column.
- 5 7. The apparatus of any of claims 1-6, comprising a rechargeable battery in a battery compartment and an electrical connector for connection to a battery eliminator.
- 8. The apparatus of any of claims 1-7, wherein said 10 removable cover is hinged to said outer casing.

1/3



2/3





JC02 Rec'd PCT/PTO 2 0 FEB 2001

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APPLICATION INFORMATION

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Title Line One:: Transportable Apparatus For Treating Men

Title Line Two:: iere's Disease

Total Drawing Sheets:: 3
Formal Drawings?:: Yes
Application Type:: Utility
Docket Number:: P/2432-38

Secrecy Order in Parent Appl.?:: No

PRIOR FOREIGN APPLICATIONS

Foreign Application One:: 9802771-7

Filing Date:: 08-19-1998

Country:: Sweden

Priority Claimed:: Yes

Source:: PrintEFS Version 1.0.1

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COMMINED DECLARATION	Unised States of AND POWER OF		LYENT APPLICATION	ON		ofgs file no.		
As a below named inventor. I decady declare that my relitebre, post office address and eigenstain are as smoot below near to my name; that I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named) of the subject matter which is claimed and for which a patter is sought on the inventors relited: TRANSPORTABLE APPARATUS FOR TREATING MENIERES DISEASE								
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I hereby claim the benefit under live 35. United States Code. \$120 of any United States applications(s) listed below and, insofar as the subject matter of each of the claims of this application is not distincted in the prior United States application in the manner provided by the first paragraph of Title 35. United States Code. \$112.1 acknowledge the duty of disclose information which is material to paragraphic in Title 37. Code of Federal Regulations. \$1.56 which became available between the filling date of the prior application and the machinal or PCT international filling date of this application.								
United States Application number		DATE OF FILING		Ipa		STATUS ormding, obsendoned)		
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I hereby appoint austomer no. 23. No. 18,510; Jerome M. Berliner - Re	SZ OSTROLENK, FA	BER, GERB & SOFI	EN, LLP, and the m	nembers of st Meilman - I	e firm. S	Samuel H. Weiner - Reg. 24,735; Signiey H.		
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I hereby declare that all statement	s made herein of my	own knowledge are to	e and that all matern	enu made or	เล่อใจภาษ	nion and belief are		
I hereby declare that all statements made herein of my own knowledge are tole and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punithable by fine of imprisonment, or both, under Section 1001 of file 18 of the United States Code, and that such willful false statements may properties the validity of the application or any passent issued thereon.								
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